510(k) Summary

I. General Information

Submitter: C2 Therapeutics, Inc.
303 Convention Way, Suite 1
Redwood City, CA 94063
Establishment Registration No. 3008780134

Contact Person: Peter Garcia-Meza
President & CEO
650-521-5304

AUG 2 2 2013

Date Prepared: June 10, 2013

II. Product Classification

Device Name: CryoBalloon Focal Ablation System

Common Name: Cryosurgical Unit, Cryogenic Surgical Device

CFR Classification: 21 CFR§878.4350(a)(2)

Product Code: GEH

III. Predicate Device

- CryoBalloon Ablation System – K101825

IV. Product Description

The CryoBalloon Focal Ablation System (modified device) is a cryosurgical unit with a nitrous oxide cooled balloon probe intended to focally destroy unwanted tissue by application of extreme cold. The system is a single-patient use device and is intended for use with commercially available endoscopes with a minimum working channel inner diameter (ID) of 3.7 mm. The handle releases the nitrous oxide, which inflates the balloon probe at the end of the catheter. The pre-inflated balloon probe comes in contact with tissue and unwanted tissue is visualized through the balloon wall via the endoscope. Tissue selection is aided through the handle and focal distribution of nitrous oxide ablates the unwanted tissue. Nitrous oxide is fully contained within the balloon probe and exits the patient through the proximal end of the catheter. The system is comprised of the following main components:

- CryoBalloon Focal Ablation Catheter (REF FG-1009). The catheter is supplied sterile.
- CryoBalloon Focal Ablation Handle (REF FG-1007). The handle is supplied non-sterile.
- CryoBalloon Ablation Cartridge (REF FG-1010) contains liquid nitrous oxide. The cartridge is disposable and is supplied non-sterile.

V. Indications for Use

The CryoBalloon Focal Ablation System is intended to be used as a cryosurgical tool for the destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.

VI. Rationale for Substantial Equivalence

The CryoBalloon Focal Ablation System is a modification of the CryoBalloon Ablation System (predicate device), cleared by the FDA under K101825. The primary modifications allow 1) focal destruction of unwanted tissue, and 2) enhanced ease of use. There are no changes to the materials and method of sterilization for the catheter. Both the predicate and modified devices have the same intended use and fundamental scientific technology. Both devices are compatible with endoscopes with a minimum of 3.7mm ID accessory channel.

VII. Safety and Effectiveness Information

Failure Modes and Effects Analysis (FMEA) was used to analyze the risks associated with the design modification. Non-clinical design verification activities demonstrate that the design outputs of the modified device meet the design input requirements. The minor differences between the CryoBalloon Focal Ablation System and the predicate device do not raise new questions of safety or effectiveness.

VIII. Conclusion

The CryoBalloon Focal Ablation System has the same intended use as the CryoBalloon Ablation System (K101825). In addition, it has identical indications, technological characteristics, principle of operation, and mechanism of action as the predicate device. Thus, the CryoBalloon Focal Ablation System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Peter Garcia-Meza
President & CEO
C2 Therapeutics, Incorporated
303 Convention Way, Suite 1
Redwood City, California 94063

Re: K131523
Trade/Device Name: CryoBalloon Focal Ablation System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: July 15, 2013
Received: July 23, 2013

Dear Mr. Garcia-Meza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C2 Therapeutics, Inc. | Special 510(k) CryoBalloon Focal Ablation System

Indications for Use Statement

510(k) Number (if known): TBD

Device Name: CryoBalloon Focal Ablation System

Indications for Use:

The C2 Therapeutics CryoBalloon Focal Ablation System is intended to be used as a cryosurgical tool for the destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.

Prescription Use (Part 21 CFR 801 Subpart D)	✓	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K131523